

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

APOTEX, INC.,

Plaintiff,

v.

CEPHALON, INC., et al.,

Defendants.

CIVIL ACTION

No. 2:06-cv-2768

Goldberg, J.

October 6, 2010

MEMORANDUM OPINION

I. Introduction

Before the Court is a patent claim construction pursuant to Markman v. Westview Instruments, Inc., 517 U.S. 370, 388-91 (1996). The invention at issue is a pharmaceutical composition comprising modafinil in the form of particles of defined size.

This case is one of many separate lawsuits currently before the Court and consolidated under the caption In re Modafinil. The lawsuit commenced on June 26, 2006, with the filing of the original complaint, which raised patent claims regarding Cephalon's RE'516 patent for Provigil®¹ and antitrust claims against Cephalon and four generic drug defendants. Since that time, the original

¹ Provigil® is a prescription drug used to promote wakefulness in adults with sleep disorders such as shift work disorder, obstructive sleep apnea and narcolepsy. The Generic Defendants originally asserted that they had non-infringing generic versions of Provigil® which they intended to market. The settlements ultimately reached in the underlying patent infringement case prohibited the Generic Defendants and Apotex from selling generic versions of Provigil®. (Apotex Second Am. Comp., ¶¶ 39, 51, 147; U.S. Patent No. RE37,516 E (filed Apr. 1, 1999).)

complaint has been consolidated with a separate complaint filed by Apotex regarding a second Cephalon patent - '346, also relating to Provigil®. Thereafter, Apotex filed an amended complaint and a second amended complaint, the latter of which raises the patent claim construction issues before the Court. Apotex has moved for a declaratory judgment, alleging that its drug, Abbreviated New Drug Application 77-667, a generic form of Provigil®, does not infringe on Cephalon's RE'516 patent or the '346 patent.

On July 16, 2010, the parties submitted their proposed claim constructions and respective briefs. The parties agreed on the claim construction for the '346 patent and also agreed to all but three constructions, which affect seven different claims, on the RE'516 patent. A Markman hearing was held on September 14, 2010, wherein no witnesses were called and counsel set forth their respective positions.

II. The Patent

The RE'516 patent covers a pharmaceutical composition of modafinil in the form of particles, of which 95% have a diameter less than 200 microns (μm). Modafinil was known for decades before Cephalon sought the RE'516 patent and consequently, the RE'516 patent could only be designed to cover a new, unique form or usage of the previously known drug. Hence, the RE'516 patent was designed to cover modafinil of a certain particle size, which produced a predictable bioavailability and potency in humans. The claims at issue are set forth verbatim below:

1. A pharmaceutical composition comprising a substantial homogeneous mixture of modafinil particles, wherein at least about 95% of the cumulative total of modafinil particles in said composition have a diameter of less than about 200 microns (μm).
2. The composition of claim 1 wherein said particles have a median diameter

range of between 2 μm and about 60 μm .

7. A pharmaceutical composition in an oral unit dose form comprising:
an amount of modafinil effective to alter a somnolent state of a mammal upon oral administration,
said amount of modafinil being in the form of solid modafinil particles,
said particles having a size distribution wherein at least about 95% of the cumulative total of said particles have a diameter of less than about 200 microns (μm).
8. The composition in unit dose form of claim 7 wherein said effective amount comprises particles have a median diameter range between about 2 μm and about 60 μm .
13. A pharmaceutical composition according to claim 7, further comprising additional modafinil particles in excess of said effective amount.
14. A pharmaceutical composition according to claim 13 wherein said additional modafinil particles represent about 10-15% of said effective amount of modafinil.
16. A method of treating a mammal diagnosed with a modafinil-responsive disease or condition selected from the group consisting of narcolepsy, Parkinson's disease, urinary incontinence, or Alzheimer's disorder,
said method comprising administering an amount of modafinil, as one or more oral unit doses, to said mammal,
said oral unit dose comprising:
an amount of modafinil effective to treat said modafinil-response disease or condition of said mammal upon oral administration,
said amount of modafinil being in the form of solid modafinil particles,
said particles have a size distribution wherein at least about 95% of the cumulative total of said particles have a diameter of less than about 200 microns (μm).

From these seven claims, the parties dispute three discrete issues: what "95% of the cumulative total of modafinil/said particles" encompasses; how diameter and size distribution of the particles is measured; and whether agglomerates fall within the definition of a particle.

III. Applicable Precedent

Patent infringement cases typically involve a two-part analysis. The first step, known as the “claim construction” involves a determination of the meaning and the scope of any disputed claims. Because a patent is a written instrument, judges, not juries, must interpret the words of the patent’s claims. Markman, 517 U.S. at 388-89. In short, claim construction is a matter of law to be determined by the court. Four main sources should be considered in analyzing a claim: (1) the words of the claims themselves, (2) the specification,² (3) the prosecution history, and, if necessary, (4) “extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.” Phillips v. AWH Corp., 415 F.3d 1303, 1314 (Fed. Cir. 2005), cert. denied, 546 U.S. 1170 (2006) (citations omitted).

The claims analysis begins and remains focused on the language of the claims themselves because that is what the inventor used to describe his invention. Interactive Gift Express, Inc. v. Compuserve Inc., 256 F.3d 1323, 1331 (Fed. Cir. 2001) (citing 35 U.S.C. § 112, ¶ 2); Sipco LLC

² The required contents of the specification are set forth in 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and processing of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

35 U.S.C. § 112.

v. Toro Co., No. 08-505, 2009 WL 330969, at *1 (E.D.Pa. Feb.11, 2009). As the Federal Circuit has explained:

Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim. The construction that stays true to the claim language and most naturally aligns with the patent’s description of the invention will be, in the end, the correct construction.

Phillips, 415 F.3d at 1316 (quoting Renishaw PLC v. Marposs Societa’ per Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1998)). “[A] patentee is free to be his own lexicographer,” and “any special definition given to a word must be clearly defined in the specification.” Markman v. Westview Instruments, Inc., 52 F.3d 967, 980 (Fed. Cir. 1995) (en banc), aff’d, 517 U.S. 370 (1996).

In the event that the patentee has not defined his own terms, claim language is generally given its “ordinary and customary meaning,” which is what it would mean to a “person of ordinary skill in the art in question at the time of the invention.” Phillips, 415 F.3d at 1313 (citing Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1116 (Fed. Cir. 2004)); see also Elbex Video, Ltd. v. Sensormatic Elecs. Corp., 508 F.3d 1366, 1371 (Fed. Cir. 2007) (“claim terms are entitled to a ‘heavy presumption’ that they carry their ordinary and customary meaning to those skilled in the art in light of the claim term’s usage in the patent specification.”). The context in which a term is used in the claim can also be “highly instructive,” and terms are normally used consistently throughout the patent. Phillips, 415 F.3d at 1314; Sipco LLC, at * 2.

The Federal Circuit has emphasized the importance of the specification in claim construction. Id. at 1315. “[C]laims must be read in view of the specification, of which they are a part.” Markman, 52 F.3d at 979. The specification’s written description of the invention “must be clear and complete enough to enable those of ordinary skill in the art to make and use it.” Vitronics Corp.

v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). Indeed, the specification is the “single best guide to the meaning of a disputed term.” Phillips, 415 F.3d at 1315 (quoting Vitronics, 90 F.3d at 1582).

The prosecution history also demonstrates to the court what the inventor did and did not intend to include in his patent.

[Although the prosecution history] often lacks the clarity of the specification and thus is less useful for claim construction purposes . . . the prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.

Phillips, 415 F.3d at 1317. Accordingly, the court examines “the patent’s prosecution history, when placed in evidence, to determine whether the inventor disclaimed a particular interpretation of a claim term during the prosecution of the patent.” Ventana Med. Sys., Inc. v. Biogenex Labs., Inc., 473 F.3d 1173, 1182 (Fed. Cir. 2006).

In addition, “extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art,” may be consulted. Phillips, 415 F.3d at 1314 (quoting Innova, 381 F.3d at 1116). However, because the universe of extrinsic evidence is boundless and such evidence is not created at the time of the patent or for the purpose of explaining the patent’s scope, it is considered less reliable than intrinsic evidence. Id. at 1318-19. Therefore, extrinsic evidence should be used only when intrinsic evidence is insufficient to resolve claim interpretation disputes.

Lastly, as a general rule, the patent language must not be rewritten even when it may be clearer if done so. Helmsderfer v. Bobrick Washroom Equip., Inc., 527 F.3d 1379, 1383 (Fed. Cir. 2008). An attempt to clarify could mistakenly add or subtract requirements. If the inventor or his

attorney could not get it right, it is not for the court to correct. See K-2 Corp.v. Salomon S.A., 191 F.3d 1356, 1364-65 (Fed. Cir. 1999). In other words, courts should avoid the temptation to write claim language in what appears to be a better way. Adherence to the original meaning of the patentee whenever possible is the paramount principle. Autogiro Co. of America v. United States, 384 F.2d 391, 396 (Ct. Cl. 1967)(“Courts can neither broaden nor narrow the claims to give the patentee something different than what he has set forth.”); Sipco LLC, at *3-4.

IV. Claim Construction

A. 95% of the Cumulative Total of Modafinil Particles

1. Independent Claims

The specific language in dispute and the parties’ proposed constructions are set forth below:

CLAIM	CLAIM TERM	APOTEX’S PROPOSAL	CEPHALON’S PROPOSAL
1	“about 95% of the cumulative total of modafinil particles in said composition”	approximately 95% of the aggregate of the individual percent values for all measurable particles in the composition based on a volume distribution	approximately 95% cumulative of modafinil particles in the composition based on a volume distribution
7	“about 95% of the cumulative total of said particles”	approximately 95% of the aggregate of the individual percent values for all measurable particles in the oral unit dose form based on a volume distribution	approximately 95% cumulative of said modafinil particles based on a volume distribution
16	“about 95% of the cumulative total of said particles”	approximately 95% of the aggregate of the individual percent values for all measurable particles in the oral unit dose based on a volume distribution	approximately 95% cumulative of said modafinil particles based on a volume distribution

The parties agree that the RE'516 patent covers 95% of the cumulative total of modafinil particles under 200 μm . The parties dispute, however, what the 95% is measuring. Apotex asserts that the 95% critical value is measured as 95% of all measurable modafinil particles.

Cephalon agrees that claim 1 allows for 95% of all measurable modafinil particles. Cephalon, however, posits that claims 7 and 16, added in the reissue patent, were intended to broaden the patent's scope. Cephalon's theory is that the 95% critical value only applies to the effective amount of modafinil, which is between 50 mg and 700 mg a day. RE'516 col.10 l.65-67 (emphasis added). Under Cephalon's construction, in a 100 mg pill, for example, the 95% critical value could apply to only 50 mg, the minimum effective amount. This would allow the remaining 50 mg of modafinil in the pill to be of any particle size. Cephalon's construction essentially allows the amount of modafinil measured by the 95% critical value to be any amount greater than 50 mg but less than 100 mg for a 100 mg pill and any amount greater than 50 mg but less than 200 mg for a 200 mg pill. This construction allows for an undetermined amount of modafinil of undefined particle size in each pill.

The specification of the patent itself is instructive in resolving this dispute. The patentee, Cephalon, defined "the term 'percent cumulative,' when used in reference to the size of modafinil particles, . . . [as] an aggregate of the individual percent values for all measurable particles measured at specified diameters." RE'516 col.2 l.43-46 (emphasis added). In 1999, Cephalon acted as its own lexicographer and decided that the percent cumulative was a percent of the total measurable particles. Consequently, Cephalon cannot now claim that they intended to mean that the percent cumulative was actually a percent of the effective amount of modafinil. Cephalon's intended meaning of the term "percent cumulative" is abundantly clear from their own definition.

The specification is littered with statements demonstrating the need for modafinil particles of a defined size. For example:

- “[a]cetamide derivative having defined particle size.” RE‘516 title.
- “[o]ur invention discloses a pharmaceutical composition comprising modafinil in the form of particles of a defined size, and the use of such composition. We have discovered that the size of modafinil particles is important.” RE‘516 col.2 l.7-13;
- “‘pharmaceutical composition’ . . . comprises modafinil of a defined particle size.” RE‘516 col.4 l.6-8;
- “[t]he invention results from our discovery that the particle size, and the consistency of the particle size, of modafinil can have a significant effect on its potency and safety profile.” RE‘516 col.4 l.54-56;
- “[p]otency is increased [because] smaller average particle size . . . [and] dosing with consistent and defined particles allows for greater reliability” RE‘516 col.5 l.21-27; and
- “[t]hese results implicated the consequences of different particle sizes and the importance of controlling modafinil particle size.” RE‘516 col.9 l.38-40.

Cephalon’s position that the 95% critical value is only 95% of the effective amount of modafinil, not 100% of the measurable modafinil in the pill, simply does not comport with the specification language noted above. The specification reiterates many times the need for the modafinil particles to have a defined size, because the particle size directly correlates to the bioavailability of the drug. If we were to adopt Cephalon’s proposed construction, part of the drug would contain modafinil of a defined particle size and the other part an unknown amount of modafinil of an unknown particle size. This construction would be contrary to both the percent cumulative definition and the specification language.

Finally, the patent prosecution history not only supports Apotex’s proposed claim construction but it also directly contradicts Cephalon’s proposed claim construction and distinction

between claim 1 from claims 7 and 16. The patentee’s reissue declaration states that the purpose for seeking the reissue patent was the failure to initially claim “pharmaceutical compositions and methods comprising a unit dose of modafinil particles.” RE‘516 reissue declaration. The declaration does not contain language broadening the scope of the patent. To the contrary, the reissue patent examiner noted that additional claims in the RE‘516 patent were allowable because “[t]he newly added claims are supported by the original specification and further limit the scope of the claimed compositions.” RE‘516, notice of allowance, at 6221.

Accordingly, the intrinsic record supports Apotex’s proposed claim construction for claims 1, 7 and 16, which we will adopt, in that the 95% critical value applies to 100% of measurable modafinil particles, not 95% of the effective amount of modafinil.

2. Dependent Claim

The parties dispute whether the 95% critical value applies to modafinil particles in excess of the effective amount. The claim language at issue and each parties’ proposed claim construction are as follows:

CLAIM	CLAIM TERM	APOTEX’S PROPOSAL	CEPHALON’S PROPOSAL
13	“additional modafinil particles in excess of said effective amount”	more modafinil particles, which have a size distribution wherein at least approximately 95% of the aggregate of the individual percent values for all measurable particles in the oral unit dose have a diameter less than about 200 microns (µm), beyond the effective amount of modafinil as defined in Claim 7	more modafinil particles beyond the effective amount of modafinil defined in claim 7

Claim 13 begins with “[a] pharmaceutical composition according to claim 7,” thus rendering the claim construction dependent upon our construction of claim 7. RE’516 col.11 l.24. “[A] claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all limitations of the claim to which it refers.” 35 U.S.C. § 112, ¶ 4.

Given claim 13's direct reference to claim 7 and the terms set forth therein, claim 13 is a dependent claim. Therefore, claim 13 must be further limiting than claim 7 and must incorporate all of the limitations set forth in claim 7. Applying the language of claim 7 as we have construed it, only Apotex’s proposal is possible. The 95% critical value applies to all modafinil particles, including amounts in excess of the effective amount.

B. How Particle Size is Measured

The parties dispute how the modafinil particle sizes are to be measured. Apotex proposes that any conventional method of measurement is allowable while Cephalon argues that only a Hiac/Royko machine can be used. The specific language in dispute and the parties’ proposed constructions are set forth below:³

³ The bracketed language denotes language that is understood to apply to the claim, but is not actually written into the claim.

CLAIM	CLAIM TERM	APOTEX'S PROPOSAL	CEPHALON'S PROPOSAL
1, 2, 4, 8, 16	"diameter"	value represented by the diameter of a sphere having the same volume [as measured by conventional methods known to those of skill in the art, including sieving and laser diffraction particle size analysis]	value represented by the diameter of a sphere having the same volume, as measured by Hiac/Royko Model 9064 sizing counter or a comparable instrument
7,16	"size distribution"	volume distribution, based on particle size as represented by the diameter of a sphere having the same volume [as measured by conventional methods known to those of skill in the art, including sieving and laser diffraction particle size analysis]	volume distribution, based on particle size as represented by the diameter of a sphere having the same volume, as measured by Hiac/Royko Model 9064 sizing counter or a comparable instrument

None of the claims at issue state that a specific measuring device or method must be used to determine whether or not 95% of all of the modafinil particles are less than 200 μm . We, therefore, turn to the specification, which states, "[m]easurements obtained using instruments and techniques developed by Hiac/Royko are preferred." RE'516 col.7 l.55-56. The word "preferred," however, suggests that it is the best of several methods allowable, not the only one. Indeed, the specification includes other language which states just that - "[t]he size of the particle can be determined, e.g., by the methods provided below, and by conventional methods known to those of skill in the art." RE'516 col.2 l.49-52. The specification also states, "that the size of the modafinil particles may be determined by any of several conventional methods. . . ," and goes on to describe how conventional methods, aside from the Hiac/Royko, can be used to measure the particles at issue. RE'516 col.7 l.32-67, col.9 l.63 - col.10 l.14.

Although the Hiac/Royko is listed as the preferred method, such an embodiment cannot be read into the claim as being the only acceptable embodiment. Phillips, 415 F.3d at 1323. Given that we cannot import Cephalon’s preference from the specification into a requirement in the claim, and the clear statements in the specification which support Apotex’s proposition that any conventional measurement method can be used, the claims will be construed accordingly.

C. Definition of a Particle

The final issue is whether or not the term “particle” includes agglomerates. The specific language in dispute and the parties’ proposed constructions are set forth below:

CLAIM	CLAIM TERM	APOTEX’S PROPOSAL	CEPHALON’S PROPOSAL
1, 2, 7, 8, 13, 14, 16	“modafinil particles”/ “said particles”/ “particles”	aggregated physical units of modafinil [could include some agglomerates]	grains or pieces of modafinil

Here, Cephalon acted as its own lexicographer and defined particle as “an aggregated physical unit of acetamide compound, i.e., a piece or a grain of acetamide.” RE’516 col.2 l.14-16. At the Markman hearing, despite the two proposed constructions above, both parties agreed that the definition in the patent would be an acceptable claim construction. (N.T. 9/14/10, pp. 138-39, 141.) Given the parties’ agreement and the express language of the specification, as drafted by Cephalon, we will construe these claims in light of the definition provided.

While the parties have gone to great lengths in advocating whether agglomerates should be included within the definition of a particle, we find that such a distinction is impossible to make at this juncture. The claim language, specification and prosecution history are silent on the issue of

inclusion or exclusion of agglomerates. Turning to extrinsic evidence, the parties' experts opine not only opposing views on inclusion or exclusion, but they also offer very different definitions for the term agglomerate. Given the lack of assistance we found in the extrinsic evidence, and our obligation not to clarify or rewrite claim language, even if such a rewrite would make the claim clearer, we are construing the claim only in light of the patentee's definition. See Helmsderfer, 527 F.3d at 1383; K-2 Corp., 191 F.3d at 1364-65.

Finally, we note that all of the conventional methods used for measuring the diameter of modafinil "units" at issue here result in a particle size measurement. See section B supra. Thus, we need not resolve the inclusion or exclusion of agglomerates, because all the methods result in a particle size measurement, which is the crux of this patent and this patent infringement suit.

For the foregoing reasons, the claims shall be construed as stated in the following Order.